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October 20, 2014

Via ECF
Honorable Sterling Johnson, Jr.
United States District Judge
U.S. District Court, E.D.N.Y.
225 Cadman Plaza East
Brooklyn, New York 11201

Re: Case No. 08-cv-3096; *United States ex rel. Hanks v. Amgen et al.*

Dear Judge Johnson,

As per the Court's October 8, 2014 Order, all Defendants submit this joint response to Relator Hanks' October 15, 2014 letter brief (Dkt. 158).

Despite requesting leave to file additional briefing on the pending Motions to Dismiss "in response to some of the arguments we've heard today" (Tr. 28/19-21), Hanks' letter is simply a rehash of his previously filed Opposition ("Opp") (Dkt. 150), with some additional case citations that largely misstate the law. Hanks' letter ignores Defendants' citations to directly-on-point precedent of this Court and the Second Circuit and does nothing to address the fundamental defects of his claims. Hanks admits he is really seeking a ticket to discovery, hoping to discover something that would support his vague allegations. Opp. at 5. But as Judge Korman made clear in *U.S. ex rel. Polansky v. Pfizer, Inc.*, parties are not permitted to conduct discovery when they do not first satisfy Rule 9(b), because "[w]hen a plaintiff does not specifically plead the minimum elements of his allegation, it enables the plaintiff to learn the complaint's bare essentials through discovery and may needlessly harm a defendant's goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, are baseless allegations used to extract settlement." 2009 U.S. Dist. LEXIS 43438, at *30 (E.D.N.Y. May 22, 2009).

In response to the specific points in the letter, Hanks' claims should be dismissed in full, and his request to amend a sixth time denied, for the following reasons.

1. Defendants Have No Reporting Duty, and on the Face of the Complaint the AKS Safe Harbor Protects the Rebates and Discounts At Issue As a Matter of Law. Hanks continues to seek to confuse the straightforward application of the plain language of the discount safe harbor regulation and refuses to recognize that the purpose of the safe harbor is to cover this very common, permissible business arrangement. *See* 64 Fed. Reg. 63518, 63529 (Nov. 19, 1999); *see also* OIG Fact Sheet, "Federal Anti-Kickback Law and Regulatory Safe Harbors" (November 1999) (noting Congress authorized the Department of Health and Human Services to issue regulations designating "safe harbors" for various business arrangements to address healthcare providers' concern that AKS would prohibit "relatively innocuous – and in some cases even beneficial – commercial arrangements") (*available at* http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm).

Despite the clear instruction in the discount safe harbor that the buyer (or, for U.S. Oncology Specialty, L.P. ("USOS"), the seller) need only provide information regarding discounts and rebates to the government *upon request*,[1] Hanks persists in incorrectly arguing that Defendants had an affirmative obligation to report rebates and discounts. Hanks further contends that each and every claim Defendants submitted was false because they did not report on the claim form the net acquisition costs for the drugs. These positions are frivolous. Hanks still has not cited any regulation or other authority that imposes such obligations on Defendants, making it not even plausible under Rule 8(a) that Defendants' alleged failure to report violated the FCA.

Moreover, Hanks' contention that "[w]hether the rebates. . . were reportable or fit within a safe harbor . . . raises a question that cannot be decided on a motion to dismiss" is simply wrong, because his allegations establish on the face of the Complaint that the safe harbor applies. *See Mercer v. Gupta*, 712 F.3d 756, 795 (2d Cir. 2013) (safe harbor in the Securities Exchange Act could be raised on a motion to dismiss "if the defense is based on facts appearing on the face of the complaint"). Here, the Complaint establishes that Defendants are *not* cost report filers, FAC ¶ 143, and therefore are not required to report discounts as a matter of law. Br. at 11-14. The Complaint also establishes that the discount and rebate terms were "fixed" because the Amgen Portfolio Contract set forth the rebate structure in writing.[2] *See* FAC, Ex. 1; Physician Practice Defendants' Reply Brief ("Reply") (Dkt. 151) at 1-2. Hanks' claims therefore fail by straightforward application of Rule 12(b)(6).

Hanks not only fails to provide any support for his fallback position that the terms of the discounts were not "fixed," but also continues to inexplicably ignore the explicit language of the commentary to the discount safe harbor final regulation, which provides that the safe harbor applies "even though the exact dollar amount of the rebate may not be known until the rebate is paid," and that "[i]n some circumstances, a rebate may be paid only after some number of successive purchases of particular goods or services." 64 Fed. Reg. 63518, 63529 (Nov. 19, 1999); *see also* Reply at 1.

Moreover, Hanks' attempt to avoid the impact of the 2013 OIG Advisory Opinion by asserting it is not binding precedent misses the point. Along with the 1999 preamble, the 2013 Opinion provides strong support that the government recognizes the legality of the discount safe harbor as applied to tiered rebate programs, even if the exact dollar amount of the rebate may not be known until a later time or the discount percentage level increases when the buyer makes additional purchases during an extended period. OIG opinions are entitled to deference as persuasive authority. *United States v.*

[1] 42 C.F.R. § 1001.952(h)(1)(iii)(B); *see also, e.g.,* Physician Practice Defendants' Brief in Support of Motion to Dismiss ("Br.") (Dkt. 149), at 12-14.

[2] The instant case therefore differs materially from *U.S. ex rel. Bartlett v. Ashcroft*, which involved disputed facts about a different safe harbor, and where the Court noted that "of critical importance, Defendants have not argued that the pertinent payments fit within the safe harbors of the Anti-Kickback Statute." 2014 U.S. Dist. LEXIS 116432, at *49 (W.D. Pa. Aug. 21, 2014).

Mead Corp., 533 U.S. 218, 221 (2001) (internal citation omitted). But – to be clear – the Court does not need to rely on the OIG opinion in any event, given the express language of the safe harbor.[3]

Finally, Relator continues to allege that "collateral" practices such as "overfill" did not qualify for safe harbor protection. However, as Defendants have previously explained, the allegations regarding these miscellaneous practices fail because they are not pled with particularity as required by Rule 9(b). Br. at 23-24; Reply at 3-7.[4] Relator offers no response to this.

2. The FCA's First-to-File Rule Jurisdictionally Bars Claims Against USOS and Other Defendants.[5] Hanks' first argument—that USOS "fails to cite to a single Second Circuit case that supports the proposition that the first-to-file bar applies to a related corporate entity"—misses the point. Every circuit to address this issue has held that the bar applies in this circumstance. USOS Br. (Dkt. 149-1) at 9. Hanks cites to no contrary authority because there is none.

Hanks' second argument—that the bar does not apply because his operative complaint has a perfunctory list of financial incentives distinct from Piacentile—falls flat as well. First, Piacentile also alleges a perfunctory list of other "financial incentives." No. 04-03983, Dkt. 12 ¶ 135. Second, Hanks' allegedly distinct incentives are not even pled against USOS—a distributor. *See* Compl. ¶¶ 181-96, 205, 207-210 (referring to the Physician Practices)). Third, even if they are pled against USOS in the operative complaint, they are plainly not pled against USOS in Hanks' First Amended Complaint (Dkt. 26 ¶ 16 ("rebates" only))—the first time Hanks pled a claim against USOS. Hanks cannot rely on other allegedly unlawful incentives, added by amendment, to create jurisdiction where there was none before. *U.S. ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co.*, 782 F. Supp. 2d 248, 260 (E.D. La. 2011). More fundamentally, once Piacentile alleged a scheme involving Amgen's payment of illegal remuneration to USON to induce the purchase of Aranesp, Neupogen, Neulasta and Epogen, Hanks' later-filed claim about the *same drugs* and the *same scheme* is barred "'even if that claim incorporates somewhat different details.'" USOS Br. at 8 (citing cases).

3. Relator Fails to Identify a *Single* Claim Submitted to the Government, and Otherwise Fails to Satisfy Rule 9(b) Under the Clear Precedent of the Second Circuit and this Court. Hanks devotes only a single paragraph in his letter to Rule 9(b), continuing to ignore governing Second Circuit authority and the many decisions of judges of this Court that require him to plead at least *some* detail about *some* of the allegedly false claims allegedly submitted to the government. *See Wood ex rel. U.S. v. Applied Research Assocs.*, 328 Fed. Appx. 744, 750 (2d Cir. 2009); *U.S. ex rel. Moore v. GlaxoSmithKline*, LLC, No. 06 Civ. 6047, 2013 U.S. Dist. LEXIS 165205, at *8 (E.D.N.Y. Oct. 16,

[3] Defendants cited the 2013 OIG Advisory Opinion for the first time in the Reply briefing because Hanks raised this new theory of liability related to "fixed terms" for the first time in his Opposition, after acknowledging that his initial theory of the case erroneously relied on the proposed rule rather than the final rule. (Opp. at 4 n.2.)

[4] For this same reason, *U.S. ex rel. Banignan v. Organon USA Inc.*, 883 F. Supp. 2d 277 (D. Mass. 2012) and *U.S. ex. rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112 (D. Mass. 2011) are inapposite. *See* Reply at 2-3.

[5] Certain Defendants have incorporated USOS's first-to-file arguments by reference. *See* attachments to Dkts. 149, 151.

2013) (Cogan, J.); *U.S. ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806, 2013 U.S. Dist. LEXIS 48398 (E.D.N.Y. Apr. 3, 2013) (Block, J.); *Polansky*, 2009 U.S. Dist. LEXIS 43438, at *16 (Korman, J.). Hanks cannot avoid this precedent by simply alleging a complex scheme or that Defendants have knowledge of the claims. Even in those circumstances, courts in this Circuit uniformly require detailed pleading of at least some claims. *Id.*; *see* Br. at 18-21; Reply at 6-7.[6]

Hanks seeks to excuse his inability to plead the details of even a single false claim by selectively and misleadingly quoting two cases. *See U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 2014 U.S. Dist. LEXIS 139072 (S.D.N.Y. Sept. 30, 2014); *U.S. ex rel Kester v. Novartis Pharm. Corp.*, 2014 U.S. Dist. LEXIS 127270 (S.D.N.Y. Sept. 4, 2014). But both of these cases held that a relator must plead "with a high enough degree of particularity that defendants can reasonably identify *particular false claims* for payment that were submitted to the government." *Kester*, *supra*, at *30 (emphasis added); *Bilotta*, *supra,* at *29-30 ("in this Circuit, courts have held that the complaint must provide details that identify *particular false claims*") (emphasis added). In addition, the government intervened in both of these cases and pleaded numerous details of the allegedly false claims at issue, including names of providers, dates of the claims, amounts charged, associated billing codes, and the specific government programs to which claims were submitted. *See Bilotta*, at *61-62; *Kester*, at *30-31.

Here, Hanks concedes he "has no access to a record of the claims filed by defendants" and "would have no way of knowing" what claims were actually submitted to the government, when, or in what amounts. *See* Opp. at 18. He therefore does not and cannot allege even a single false claim, and as a result his FCA claims fail *in toto* under Rule 9(b). Hanks also ignores his failure to plead the details of, *inter alia*, any medically unnecessary treatment, and his failure to separately allege particular facts as to particular defendants. Reply at 4.

4. Relators' Claims Are Barred by the FCA's Public Disclosure Bar. Hanks misreads *U.S. ex rel. Kirk v. Schindler Elevator Corp.,* 601 F.3d 94 (2d Cir. 2010). In *Kirk* the Second Circuit indicated its approval of the "on the trail" standard followed by other circuits, so that parasitic *qui tam* suits would be barred where "some branch of the government has turned its attention to the potential fraud." *Id.* at 111. That is precisely what occurred here, long before Hanks came along – through, among other things, the government audits and investigations of Amgen. Reply at 11. Hanks seizes on the phrase in *Kirk* about relators proceeding "where the government was not in a position to act," *id*., but that means where the government does not have the information to act – not where the government simply declines to intervene. Because, by the FCA's express language, the public disclosure bar *never* applies where the action is brought by the government,[7] Hanks' misreading of *Kirk* would mean that the bar would never apply in any case. Here, the government

[6] Hanks' citation to *Simington v. Lease Finance Group, LLC*, No. 10-cv-6052, 2012 U.S. Dist. LEXIS 25671, at *16-17 (S.D.N.Y. Feb. 10, 2012), is misplaced. That case involved an alleged fraudulent equipment leasing scheme, not an FCA claim; and the complaint, unlike Hanks', included detailed examples of the alleged scheme.

[7] *See* 31 U.S.C. § 3730(e)(4) (public disclosure bar does not apply where "the action is brought by the Attorney General or the person bringing the action is an original source of the information.").

acted on the claims it believed were worth pursuing – against Amgen – and (correctly) chose not to pursue claims against these Defendants.

U.S. ex rel. Kester v. Novartis Pharms. Corp. did not say that disclosures not identifying defendants by name never suffice. Instead it said that "[i]n order to bar claims against a particular defendant, the public disclosures relating to the fraud must either explicitly identify that defendant as a participant in the alleged scheme, *or provide enough* information about *the participants in the scheme such that the defendant is identifiable*…In other words, the *public disclosure must set the government squarely on the trail* of a specific defendant's participation in the fraud." No. 11 Civ. 8196 (CM), 2014 U.S. Dist. LEXIS 124761 at *27 (S.D.N.Y. Sep. 3, 2014) (emphases added; internal quotation marks and references omitted).[8] The public disclosures here referred to providers contracting with Amgen and specifically identified the drugs at issue, such that the government could have identified and pursued the counter-parties to the contracts itself, had it seen any basis to do so. Br. at 28; Reply at 11-12. This is sufficient to trigger the public disclosure bar even based on precedent relied on by Hanks. *See Banignan,* 883 F. Supp. 2d at 289 (dismissing based on disclosures that did not mention specific defendant but identified the drug and therefore the alleged scheme).

Hanks is also wrong in asserting that his post-2010 allegations survive the public disclosure bar. *Kester* temporally limited the bar after 2010 because the disclosure there was state court litigation, which was amended out of the list of qualifying public disclosures in 2010. *Kester,* 2014 U.S. Dist. LEXIS 124761, at *44-45. The public disclosures barring Hanks' claims here include federal litigation in which the government was the real party in interest, *i.e.* the prior relator cases such as *Westmoreland*, a federal OIG audit report, and news media reports – all of which are public disclosures under both pre- and post-2010 versions of the FCA.[9]

5. Hanks Should Not Be Granted a Sixth Chance to Amend. As discussed in detail in Defendants' briefing (*e.g.*, Br. at 26; Reply at 8-9), neither Hanks' Fifth Amended Complaint nor the declaration filed with his opposition brief – which largely repeats the same boilerplate, word for word, as to each of the Defendants – can cure the deficiencies in Hanks' purported claims.[10] *See Moore,* 2013 U.S. Dist. LEXIS 165205, at *8; *Mooney,* 2013 U.S. Dist. LEXIS 48398. This case should be dismissed, without discovery or leave to amend, and with prejudice.

[8] Hanks incorrectly states that, in *Kester*, no defendant was named in public disclosures; in fact, Novartis was. *Id.* at *54.

[9] Hanks does not challenge most of the Defendants' arguments that he is not an original source, instead arguing – again incorrectly – that he need not be an original source of the public disclosures, relying on *Rockwell Int'l Corp. v U.S.*, 549 U.S. 457 (2007). Nearly four years after that case, however, the Supreme Court noted that it need not decide whether "original sources" must be "the cause of the public disclosure"; clearly, it had not decided the issue in *Rockwell*. *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 131 S. Ct. 1885, 1895 n.8 (2011). And in any event, Hanks does not have the necessary direct and independent knowledge to survive the bar. *See* Br. at 31-33.

[10] Nor do the exhibits to the declaration "identify specific kickbacks," as Relator represents; the exhibits show "sales data" and updates of purchases, not rebate payments – the form of alleged kickback at issue.

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Respectfully submitted,

s/ Lawrence M. Kraus

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cc: All counsel of record (via ECF)